N THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF OKLAHOMA

JOEL FRANKS and TAMMY FRANKS, Plaintiffs, vs. APEX SURGICAL, LLC n/k/a and/or OMNI LIFE SCIENCE, INC, Defendants.	)	Case No. CIV-22-240-HE

COMPLAINT

COME NOW Plaintiffs, Joel Franks and Tammy Franks, by and through his attorney, Scott Gallagher, Little, Oliver & Gallagher, and for their cause of action against Defendants, Apex Surgical, LLC n/k/a and/or Omni Life Science, Inc., state and allege as follows:

1. Plaintiffs, Joel and Tammy Franks are residents of Okemah, Okfuskee County, Oklahoma.

2. Defendant, Apex Surgical, LLC n/k/a and/or Omni Life Science, Inc.. is or was a limited liability company organized and existing under the laws of the State of Massachusetts. In October 2005, Apex was acquired by OMNI Life Science, Inc. ("OMNI"), which is a corporation organized and existing under the laws of the State of Massachusetts with its principal place of business in Raynham, Massachusetts.

3. Defendant may be served by serving the registered agent of the corporation, Craig Hutchinson, 480 Paramount Drive, Raynham, MA 02767. Service of said Defendant as described above can be effected by certified mail, return receipt requested.

4. This claim for the defective hip is against Apex Surgical, LLC and anyone that acquired Apex thereafter including, but not limited to, Omni Life Science, Inc.

FACTUAL BACKBROUND

5. Defendant designs, manufactures, markets, sells and distributes, among other things, implantable medical devices including a modular hip system or hip replacement device.

6. Defendant's hip replacement devise is theoretically made to function in the same manner as a person's natural hip.

7. The hip implant system consists of a ball on a stem that is inserted into the thigh bone. The ball is connected to a neck, which is connected to the stem. The neck and stem are attached to one another by means of a bolt.

8. In July 23, 2004 the total replacement surgery for Plaintiff's left hip was performed by Dr. Tkach in Oklahoma City. Dr. Tkach chose and used an "Apex" hip replacement device to be used for Plaintiff.

9. Plaintiff had inserted into his left hip an Apex Mach 1 stem.

10. On or about September 24, 2020 Plaintiff felt a pop in his left hip with immediate pain and was unable to bear weight. He again sought the treatment of Dr. Tkach. Dr. Tkach diagnosed him as having a failed left hip arthroplasty having fractured the junction, having a failed left total hip arthroplasty with broken hardware and broken trunnion. Dr. Tkach removed the defective hip and hardware and replaced it on September 29, 2020.

FIRST CLAIM FOR RELIEF
(Ordinary Negligence and Gross Negligence)

Plaintiff adopts and realleges every paragraph above as if set forth verbatim herein.

11. Defendants had a duty to use reasonable care to design, manufacture, market, sell and/or distribute the hip replacement device in a condition safe for its intended purpose. By failing to exercise ordinary care in its design, manufacture, testing, quality assurance, quality control, marketing, sale and/or distribution of its hip replacement device, Apex placed Plaintiff in unreasonable danger of having its defective hip replacement device implanted, suffering extreme mental and physical pain, and then having major invasive surgery as the only means to correct the problem.

12. Defendants breached it duty to Plaintiff by failing to use reasonable care in the design and manufacturing of the hip replacement device and by failing to properly inspect or test the hip replacement device for its intended use of being implanted into Plaintiff's body. At the time the Apex device was implanted into Plaintiff, he was forty-six years old and very active.

13. Defendants breached its duty in that, upon information and belief, it knew or should have known that its defective hip replacement device was unreasonably dangerous for its intended implant purposes and failed to warn the FDA, the medical community or the public of these dangers.

14. Defendants breached its duty in failing to use proper materials reasonably suited to the manufacture or design of the hip replacement device.

15. Defendants had exclusive control over the design and manufacture of its hip replacement device. Plaintiff had no means of ascertaining the method or manner in

which the hip preplacement device was designed or manufactured, and used it in their intended manner in the same condition as it was when it left Apex's control.

16. As a direct and proximate result of said wrongdoing and negligence by Defendants, Plaintiff has incurred medical expenses that would have been unnecessary but for the defective nature of the hip replacement, has suffered months of debilitating physical and mental pain and anguish and has had to undergo a painful and invasive surgery to remove the defective hip replacement devices and replace it with an implant suitable for its purpose.

17. Upon information and belief Defendants knew or should have known of the defective nature of its hip replacement device, and yet continued to manufacture, market, sell and/or distribute the hip replacement device to maximize its sales and profits at the expense of the health, safety and well-being of Plaintiff, in conscious or reckless disregard of the foreseeable harm to Plaintiff.

SECOND CLAIM FOR RELIEF
(Strict Product Liability)

Plaintiff adopts and realleges every paragraph above as if set forth verbatim herein.

18. Upon information and belief, Defendants knew and/or should have known that there were risks and/or defects associated with the hip replacement device.

19. Defendants breached its duty to warn Plaintiff, his physician and the FDA of any and all risks and/or defects associated with the hip replacement device, thereby causing Plaintiff to essentially forfeit months of his life due to excruciating physical and mental pain.

20. The hip replacement device was defective as a result of Defendants' manufacturing process, making the hip replacement device totally inadequate and unreasonably dangerous for its intended use.

21. In addition, the hip replacement device was defective in that it was not accompanied by adequate warnings of the known or reasonably knowable risks and/or defects connected with the hip replacement device.

22. Therefore, as a direct and proximate result of said wrongdoing, Plaintiff has incurred medical expenses that would have been unnecessary but for the defective nature of the hip replacement device, has suffered months of debilitating physical and mental pain and anguish, and has had to undergo a painful and invasive surgery to remove the defective hip replacement device and replace it with another implant suitable for its purpose.

THIRD CLAIM FOR RELIEF
(Breach of Warranty)

Plaintiff adopts and realleges every paragraph above as if set forth verbatim herein.

23. Defendants expressly and impliedly warranted to the public generally, and Plaintiff specifically, that the hip replacement device was of merchantable quality and was safe and fit for the purpose intended when used under ordinary conditions and in an ordinary manner.

24. As a direct and proximate result of Plaintiff's reliance on Defendants' warranty, Plaintiff has incurred medical expenses that would have been unnecessary but for the unmerchantability of the hip replacement device, has suffered months of debilitating physical and mental pain and anguish, and has had to undergo a painful and

invasive surgery to remove the defective hip replacement device and replace it with another implant suitable for its purpose.

FOURTH CLAIM FOR RELIEF
Misrepresentation

Plaintiff adopts and realleges every paragraph above as if set forth verbatim herein.

25. Defendants misrepresented to Plaintiff and the public that its product was safe and without defect for its intended use.

26. Defendants' misrepresentation involved a material fact concerning the character and/or quality of the hip replacement device.

27. Plaintiff, by and through Dr. Tkach, who chose the device, constructively relied upon Defendants' misrepresentation to his detriment.

28. As a direct and proximate result of Plaintiff's reliance on Defendants' misrepresentation, Plaintiff has incurred medical expenses that would have been unnecessary but for his reliance on Defendants' representations concerning the merchantability and safety of the hip replacement device, has suffered months of debilitating physical and mental pain and anguish and has had to undergo a painful and invasive surgery to remove the defective hip replacement devices and replace it with another implant suitable for its purpose.

FIFTH CLAIM FOR RELIEF
(Negligence Per Se)

Plaintiff adopts and realleges every paragraph above as if set forth verbatim herein.

29. Plaintiff, as a purchaser and consumer of the hip replacement device, falls within the category of the type of persons designed to be protected by state and federal laws. Such laws are designed to prevent injuries resulting from failure to adequately warn of known or reasonably knowable risks and/or defects and failure to disclose adverse events or adverse event reports.

30. As a direct and proximate result of Defendants' negligence *per se*, Plaintiff has incurred medical expenses that would have been unnecessary but for the defective nature of the hip replacement device, has suffered months of debilitating physical and mental pain and anguish, and has had to undergo a painful and invasive surgery to remove the defective hip replacement device and replace it with another implant suitable for its purpose.

SIXTH CLAIM FOR RELIEF
(Loss of Consortium)

Plaintiff adopts and realleges every paragraph above as if set forth verbatim herein.

31. Plaintiffs Joel and Tammy Franks were married on April 25, 2002. On January 18, 2006, the Apex hip implant device failed, causing significant injuries to Plaintiff.

32. As a direct and proximate result of Defendants' actions and inactions detailed above, and the resulting injuries to his spouse, Tammy Franks has suffered the loss of society, affection, guidance, companionship and consortium in an amount to be determined at trial, for all of which Defendants are liable.

COMBINED PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for the following:

(a) Actual damages against Defendants to compensate: (i) Plaintiff for his actual medical expenses, compensation for his physical, mental pain and suffering, and emotional distress, and his lost income during the period he was incapacitated; and (ii) Tammy Franks for her loss of consortium.

(b) Costs and attorney fees, if appropriate; and

(c) All other relief to which Plaintiff may be entitled, whether at law or in equity.

Respectfully submitted,

LITTLE, OLIVER & GALLAGHER

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